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Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/754,204

01/05/01

GELBER

D

XMP 2031

HM12/0327

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EXAMINER

OZGA, B

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

03/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/754,204

Applicant(s)

GELBER ET AL.

Examiner

Brett T Ozga

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) 65-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-126 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 USC 121:

I. Claims 1-64, drawn to compositions for treating pain resulting from an inflammatory response, classified in class 424, subclass 725.

II. Claims 65-126, drawn to methods for treating pain, classified in class 424, subclass 725.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are methods for treating pain in which one does not use the compositions of Group I, and instead uses a narcotic.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Terry Kramer on 3/19/01, a provisional election was made with traverse to prosecute the invention of Group II, claims 65-126. Affirmation of this election must be made by applicant in responding to this Office

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action. Claims 1-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 65-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weisman (USP #5888514) in view of Wei et al. (Nutr. Res. (N. Y.) (1998), 18(1), 61-70), Yamakazi et al. (USP #5531992), Rechner (USP #542749) and Patwardhan (USP #5494668).

The instant application teaches a method of treating a patient suffering from pain resulting from an inflammatory response, comprising the step of administering to the patient a medicinal composition, said medicinal composition comprising: a pharmaceutical, a nutraceutical and an acceptable base. Dependent claims further limit the invention by selecting the pain relieving and anti-inflammatory agents from acetaminophen and NSAID's. They also limit by selecting the nutraceutical from a group including garlic and ascorbic acid and where the nutraceutical liver protectant is milk thistle. They also limit by choosing the joint relief agent from a group including glucosamine or chondroitin sulfate and derivatives thereof.

Weisman teaches a method of treating bone or joint inflammation and, inherently, the resulting pain comprising the step administering a composition that includes glucosamine and chondroitin sulfates and ascorbic acid. (See abstract) Weisman does not teach selecting the pain relieving and anti-inflammatory agents from acetaminophen and NSAID's. He also does not teach selecting the nutraceutical from a group including garlic or where the nutraceutical liver protectant is milk thistle. Weisman also does not teach that immune stimulation is inherently positive and does not teach that pain can reduce immune response over time.

Rencher teaches a method of treating a patient suffering from pain resulting from an inflammatory response with acetaminophen or NSAID's. (See col. 3, first full paragraph)

Yamakazi et al. teach a method of treating a patient suffering from pain and inflammatory disease with milk thistle, an immune booster. (See col. 9, fourth paragraph and Tables 3 and 4)

Wei et al. teaches a method of treating a patient suffering from inflammatory disease, which cause pain, with garlic, an antioxidant. (See abstract)

Patwardhan teaches that immune stimulation is inherently positive and that pain can reduce immune response over time. He also teaches that use of pharmacologically active plant extracts is well known. (See col. 2, last paragraph)

Examiner takes Official Notice that the applicant's claimed immune boosters, antioxidants, pharmaceuticals and nutraceuticals are well known in the art.

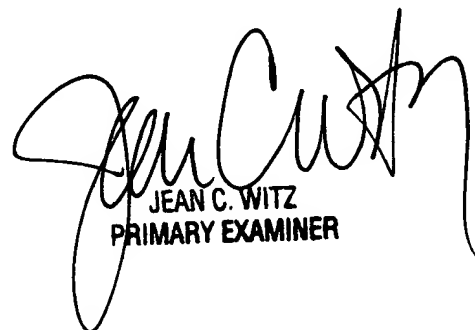
The motivation to combine the references is that each composition can treat a specific inflammatory response; combining them gives more general coverage. Also, synergism of the compositions and decrease of any deleterious effects gives one motivation to combine.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

  
JEAN C. WITZ  
PRIMARY EXAMINER